IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Michael A. Porter	Art Unit	: 1761
Serial No.	: 10/722,359	Examiner	: Anthony J. Weier
Filed	: November 25, 2003	Conf. No.	: 4715
Title	: MODIFIED OILSEED MATERIAL WITH A HIGH GEL STRENGTH		

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DECLARATION OF MICHAEL A. PORTER UNDER 37 C.F.R. §1.132

I, Michael A. Porter, hereby declare:

1. I have received a Ph.D. in Agronomy from Kansas State Univerity in the area of crop physiology and biochemistry. After 8 years, in academic research I joined Cargill Incorporated as a Seior Research Chemist. After 16 years, I am now Research Fellow and part of the Health & Food Technologies Research and Development group. The majority of this work experience with Cargill has been focused on the processing of soy protein ingredients, the resulting functionality of the produts, and the application of those ingredients in food and non-food items. The most recent period has been focused on the development of soy protein isolate products and processes.
2. I have read and reviewed Lawhon, U.S. Patent No. 4,420,425 ("the '425 patent").
3. The central process of the '425 patent involves extraction of soy flakes at 30 parts water to 1 part flakes at an approximate pH of 8, followed by centrifugation to form an extract and spent flake. The extract is then heat-treated, pre-filtered, and held at 65°C. The extract is passed over an ultrafiltration membrane with constant water addition followed by concentration. The concentrated solution is then spray dried.

CERTIFICATE OF TRANSMISSION BY FACSIMILE

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date indicated below.

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4. It is my opinion that one of skill in the art cannot accurately predict the properties of a product produced by the method of the '425 patent for several reasons, including:
    a. The lack of discussion regarding pH. The pH of the material during the ultrafiltration process was not defined or discussed in the specification, or in examples 1, 2, 3, or 4. Experimental work that has been completed in our pilot plant has shown that the solubility and viscosity of the resulting dried product are determined, in part, by the pH of the retentate during filtration. The '425 patent does not specify any pH control during the ultrafiltration process. Though the retentate was heat-treated, the retentate was unlikely to be sterilized at the temperatures used, which can lead to bacterial growth that will decrease pH. Our experience has found that treatment at 65°C for greater than 30 minutes still results in finding microbial matter. Without pH control, the properties of the finished product become more unpredictable because the protein is exposed to different pH's during processing;
    b. No mention is made of the temperature configuration of the spray drier during drying. Low temperatures during spray drying will generally be associated with higher solubility, while higher temperatures during drying will generally be associated with lower solubility. In addition, material can be dried under differing conditions. In one configuration, essentially all water is removed in a single step and all powder is directly collected as finished product. In another configuration, the material is dried so that moisture is removed in two stages, with approximately 80% of the water removed at high temperature and the remaining 15% of moisture removed at a lower temperature. The drying process may further be combined with recycling of undersized particles back to the top or bottom of the drier in order to build particle size to a larger and more uniform state. Recycled particles experience additional heating, which may also affect functional behavior. Thus, materials dried by different drying methods can have very different functional behavior as measured by solubility, viscosity, and bulk density; and

c. No mention is made of the solids content of the liquid stream fed to the spray drier. The solids content may have a distinct effect on the functional properties of the resulting soy isolate. While a general approximation may be possible from the description in Example 1, a calculation of the resulting solids is not possible. In example 1, a constant volume phase is described where 80 gals of solubilized feed is treated by ultrafiltration for 2 hours and results in a feed tank stream having approximately 1.64% solids. This is then allowed to concentrate until 160 gallons of permeate were collected. Because retentate at the end of the constant volume phase comprised 80 gallons, and 160 additional gallons were collected with the solids concentration reported to rise, it is not possible to calculate how much the concentration was increased while additional water was being added because the final volume of retentate is not described.

5. An accurate reproduction of the method, or the ability to accurately predict the properties of the resulting material, would require additional information, including:
   a. The inlet and outlet temperatures of the spray drier;
   b. The solids content of the spray drier feed stream;
   c. The pH of the liquid stream fed to the spray drier;
   d. The pH maintained in the retentate during ultrafiltration; and
   e. The configuration of the spray drier (one-stage, two-stage drying, and if fines recycling is used, where the fines are returned).
6. The specific consequences of particular processing conditions, or combinations of conditions, cannot be predicted *a priori*. Pilot work that we have done has shown that the functional properties of soy isolate change as a consequence of thermal treatments and that those thermal treatments are also influenced by the pH experienced by the proteins during processing. For example, higher temperatures would generally be associated with lower solubility and viscosity in the resulting material. The solids content may also have various effects, as higher solids content would generally be associated with higher product bulk density, while intermediate solids would generally be associated with lower bulk density, and low solids will generally be associated with high bulk densities. Thus,

many functional behaviors are partially dependent on the particle behaviors associated with setting bulk density.

7. The conditions used to spray dry the product may have a large impact on the product properties. Depending on the conditions used, it is possible to spray dry and retain the native state of proteins or to spray dry and completely denature the same proteins. These conditions affect the properties of the resulting product. This is just one example of the range of effects that may be obtained by changing various operating conditions.
8. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated: December 14, 2006

Michael A. Porter